OCT - 9 2003

510(k) Summary

K032581

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	Global Modular Replacement System Anteverted Proximal Femoral Component
Common Name:	Proximal Femoral Replacement
Classification Name and Reference:	Prosthesis, Hip, Semi-constrained Metal/Polymer Porous Uncemented 21 CFR §888.3358
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) LPH

Intended Use

Indications

Femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This component may also be used with the Distal Femoral segment components of the GMRS™ in total femoral replacement.

Contraindications

A. As Related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

B. As related to Failed Previous Prosthesis and Trauma

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

The Proximal Femoral Module of the GMRS™ is intended to be used in a cemented or press fit mode.

Device Description

It is the intention of Howmedica Osteonics Corp. to offer GMRS™ Proximal Femoral Components in an anteverted style, so both the standard and trochanteric versions will be available in left and right orientations. These new GMRS™ Proximal Femoral Components offer 15 degrees of anteversion.

The current GMRS™ proximal femoral components have the axis of their femoral neck perpendicular to the center plane of the slot formed by the two anti-rotation tabs when viewed from the distal-to-proximal direction. The subject GMRS™ anteverted proximal femoral components have the axis of their femoral neck at 75 or 105 degrees to the center

plane of the slot formed by the two anti-rotation tabs when viewed from the distal-to-proximal direction. The difference in the degrees of rotation from the currently available component is 15 degrees, which provides 15 degrees of anteversion (left or right) when implanted with the bowed press-fit stems.

The following design features are common to the new Anteverted Proximal Femoral Components, and the existing GMRS™ Proximal Femoral Components:

- These components are each available in one size.
- These components are fabricated from cast cobalt-chromium alloy that meets the requirements of ASTM standard F-75.
- 5 degree 40 minute taper angle to accept Howmedica Osteonics' modular femoral heads with the same taper
- 70mm replacement length
- porous coating and suture holes in the A-P direction for tissue attachment
- threaded insertion feature on the shoulder to allow for the use of an insertion instrument
- 26mm distal diameter
- 34mm head-neck offset

The GMRS™ Trochanteric Proximal Femoral Component has increased material in the region of the greater trochanter for surgeons who prefer an anatomically shaped component.

The Standard and Trochanteric Proximal Femoral Components of the GMRS™ may be used with the GMRS™ Connection Pieces, Extension Pieces and the Press Fit Stems with PureFix™ HA Coating in proximal femoral replacement. These products may also be used with the MRS Body components, and modular stems in proximal femoral replacement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K032581
Trade/Device Name: GMRS™ Anteverted Proximal Femoral Component
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: LPH
Dated: August 18, 2003
Received: August 21, 2003

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

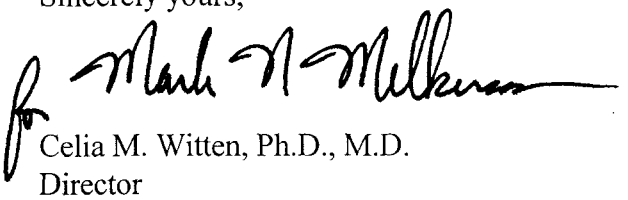
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032581

Device Name: GMRS™ Anteverted Proximal Femoral Component

It is the intention of Howmedica Osteonics Corp. to introduce an additional style of GMRS™ Proximal Femoral Component - this new style of GMRS™ Proximal Femoral Component is anteverted, and as such is available in left and right orientations. This additional style of Proximal Femoral Component is similar in design to the existing GMRS™ Proximal Femoral Components, except for 15 degrees of anteversion. Indications and contraindications for this additional style of GMRS™ Proximal Femoral Component are listed below:

Indications

Femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications. This component may also be used with the Distal Femoral segment components of the GMRS™ in total femoral replacement.

Contraindications

A. As Related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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B. As related to Failed Previous Prosthesis and Trauma

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.

- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

The Proximal Femoral Module of the GMRS™ is intended to be used in a cemented or press fit mode.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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